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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,883	03/26/2001	Jorg Peter Schur	VONKREISLER.	8618
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DANN, DORFMAN, HERRELL & SKILLMAN 1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307			YOUNG, MICAH PAUL	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

Acknowledgement of Papers Received: Amendment/Response dated 11/14/05.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 46, 48-53, 55, 57-61 and 64 rejected under 35 U.S.C. 102(b) as being anticipated by Honda (USPN 5,750,563 hereafter '563). The claims are to an antimicrobial composition consisting essentially of a polyphenols.

3. The '563 patent is drawn to a preparation comprising polyphenols, antimicrobial agents and lactic acid (abstract, col. 4, lin. 20-25). The composition comprises at least one gallic acid derivatives such as tannic acid, a flavonoid such as gossypetin and various extracts and essential oils such as camphor (col. 3, lin. 25-col. 4, lin. 26, claim 1). The components of the composition are present in concentrations from 0.1 to 20 % (*Ibid.*) These disclosures render the claims anticipated.

4. Claims 67-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Hughes et al (USPN 5,322,689 hereafter '689). The claims are drawn to an antimicrobial formulation comprising polyphenols and phenol compounds.

5. The '689 patent discloses a topical aromatic formulation comprising antibiotics, and carriers (col. 7, lin. 3-68). The carriers include humecatant/moisterizers like lactic acid, extracts

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such as camphor and eucalyptus oil and phenols such as thymol (examples). These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 56 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Honda (USPN 5,750,563 hereafter '563), Hamilton-Miller (USPN 5,879,683 hereafter '683) and Carson et al (USPN 5,416,075 hereafter '075). The claims are drawn to a composition comprising polyphenols as extracts.

9. As discussed above the '563 patent discloses an antimicrobial composition comprising polyphenols, and other active agents. The patent suggests the inclusion of extracts of an animal or vegetable origin but is silent to the specific extracts recited by the claims. However tea

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extracts (*Camellia sinensis*) have long been known for their antimicrobial properties. These properties are discussed in the '683 and '075 patents.

10. The '683 patent discloses an antimicrobial formulation comprising tea extracts (black, green or oolong) (col. 3, lin. 52-58). These formulations are used to fight infections (abstract). One of ordinary skill would be motivated to include the polyphenols of '683 into the formulation of '563 in order to fight more microbial infections.

11. The '075 patent discloses antimicrobial emulsions comprising extracts and antimicrobial compounds (abstract). The extracts include essential oils including camphor orange oil and anise oil (col. 8, lin. 38-53). A skilled artisan would have been able to follow the suggestions '563 to include vegetable and essential oils, and include the anise oil of '075 in order to add flavor and an aromatic effect.

12. A skilled artisan would have been motivated to include the extracts of both '683 and '075 into the formulation of '563 in order to improve the antimicrobial fighting effects and improve the flavor and aromatic properties of the composition. These combinations would have been made under the suggestion of '563 to include essential oils and plant/vegetable extracts into the formulation. It would have been obvious to an artisan of ordinary skill to combine these components with an expected result of a topical formulation with improved microbial fighting and aromatic properties.

13. Claims 62,63 and 66 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Honda (USPN 5,750,563 hereafter '563). The claims are drawn to a formulation comprising lactic acid, and polyphenols.

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14. As discussed above the '563 reference discloses a formulation comprising lactic acid, and polyphenols. The reference discloses the concentration of the polyphenols included but is silent to the lactic acid concentration. However applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

15. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

16. Regarding claims 63 and 66 it is the position of the Examiner that any composition without an antimicrobial component is susceptible to infection. This would extend to the carrier formulation for the '563 reference. Without the antimicrobial component the carrier composition would be susceptible to infection. It is the position of the Examiner that the '563 reference is inherently a formulation microbially perishable product containing the antimicrobial composition of the invention.

17. With these things in mind it would have been obvious to a skilled artisan to follow the teachings and suggestions of the reference in order to provide an optimized antimicrobial formulation. It would have been obvious to one of ordinary skill in the art to follow these

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suggestions and teachings with an expected result of an antimicrobial formulation useful in treating infections and preserving products.

Response to Arguments

18. Applicant's arguments filed 11/14/05 have been fully considered but they are not persuasive. Applicant argues that:

- a. The '563 patent does not anticipate the claims
- b. The '689 patent does not anticipate the claims
- c. Since the '563 patent do not anticipate there is no motivation to combine the '075 and '683 patents.
- d. The '563 patent further does not obviate the claims.

19. Regarding arguments a. and b., it remains the position of the Examiner that both references continue to anticipate. The '563 patent teaches an antimicrobial formulation comprising polyphenols such as gallic acid, gossypetin, tannic acid and biological extracts (col. 36-45). The composition further comprises the extract of culture liquor of lactic acid bacteria, which would contain lactic acid, and not the bacteria. It was never asserted by the Examiner that kojic acid was a polyphenols. The formulation contains sufficient disclosures of polyphenols. The reference also teaches that components would be present in concentrations from 0.1-10% by weight, reading on the instant claims. It remains the position of the Examiner that these disclosures are sufficient to render the claims anticipated. Regarding the '689 reference, again the reference teaches an antimicrobial formulation containing thymol, phenol, and lactic acid (examples and col. 9, lin. 48). Applicant argues tat the camphor and eucalyptus oils would provide a detriment to the invention, however, applicant further points to the specification where

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such substances are successfully put to use in the carrying out of the invention. Regardless the composition of the '689 reference is an antibiotic like that of the instant invention, and contains the same components as the instant invention used in the same field of endeavor. For these reasons at least the claims remain anticipated by the art.

20. Regarding argument b., applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the prior art reference provide suggestions to the inclusion of extract, specifically biological and botanical extracts (col. 3, lin. 44-46). The '683 and '075 establish the knowledge in the art of extracts used in antimicrobial formulations. The '683 patent provides the tea extracts while the '075 provides the essential oils recited in the claims. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). For these reasons the claims remain obviated by the combination of the art.

Regarding argument d., it remains the position of the Examiner that the '563 patent provides sufficient suggestion to obviate the claims reciting specific concentrations of the components. Applicant is reminded that is not novel or invention to determine the optimal

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working ranges of a formulation barring a showing of criticality to those range and a showing of unexpected results. Further, the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). For these reasons at least the claims remain obviated by the art.

Conclusion

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608.

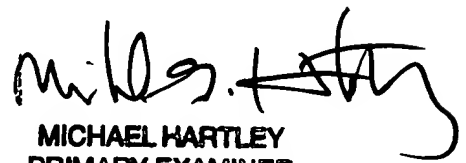
The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MP Young

Micah-Paul Young
Examiner
Art Unit 1618


MICHAEL HARTLEY
PRIMARY EXAMINER